IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9076

Bartle, J. May 29, 2013

Wendy Isakson ("Ms. Isakson" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

---

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Zachary E. Isakson and Ryan D. McDonnell, Ms. Isakson's children, also have submitted derivative claims for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In February, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, W. Marcus Brann, M.D., F.A.C.C. Dr. Brann is no stranger to this litigation. According to the Trust, he has signed at least 765 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated July 26, 2002, Dr. Brann attested in Part II of Ms. Isakson's Green Form that claimant suffered from moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral

---

3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

regurgitation, an abnormal left ventricular dimension, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 40% to 49%.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $641,205.[5]

In the report of claimant's echocardiogram, the reviewing cardiologist, James D. Watson, M.D., F.A.C.C., stated, "The degree of mitral regurgitation seen is 31 percent by the Singh method." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In April, 2006, the Trust forwarded the claim for review by one of its auditing cardiologists.[6] Although the auditing cardiologist accepted Dr. Brann's finding of moderate

---

4. Dr. Brann also attested that claimant suffered from New York Heart Association Functional Class IV symptoms. This condition is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left ventricular dimension, an abnormal left atrial dimension, or a reduced ejection fraction, each of which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

6. The name of the auditing cardiologist has been redacted from the record before us.

mitral regurgitation, pursuant to Court Approved Procedure ("CAP") No. 11, the Consensus Expert Panel subsequently reviewed Ms. Isakson's claim and determined that it should be re-audited because the "[d]egree of [mitral regurgitation] appears less than moderate by Singh criteria."[7] In August, 2006, the Trust informed Ms. Isakson that it had accepted the Consensus Expert Panel's recommendation that her claim be re-audited.

In September, 2006, the Trust forwarded the claim for review by another auditing cardiologist, Craig M. Oliner, M.D. Dr. Oliner concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Oliner observed:

> There is mild [mitral regurgitation]. The RJA's are freeze frames that do not represent the mild [mitral regurgitation] seen in real time. Most of the RJA's include substantial non-[mitral regurgitant] low velocity signal. Color gain is excessive and Nyquist is borderline low at 51cm/sec.

Based on Dr. Oliner's finding that claimant did not have moderate mitral regurgitation, the Trust issued a post-audit determination denying Ms. Isakson's claim. Pursuant to the Rules

---

7. The Consensus Expert Panel consists of three cardiologists, one designated by each of Class Counsel, the Trust, and Wyeth. See Pretrial Order ("PTO") No. 6100 (Mar. 31, 2005). We approved creation of the Consensus Expert Panel to "monitor the performance of the Auditing Cardiologists and to develop procedures for quality assurance in the Audit of Claims for Matrix Compensation Benefits." Id.

for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[8] In contest, claimant argued that the Green Form she previously submitted provided a reasonable medical basis for Dr. Brann's representation that Ms. Isakson had moderate mitral regurgitation.

The Trust then issued a final post-audit determination, again denying Ms. Isakson's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Isakson's claim should be paid. On February 28, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7011 (Feb. 28, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on May 17, 2007. Under the Audit Rules, it is within the Special Master's discretion to

---

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Isakson's claim.

appoint a Technical Advisor[9] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

---

9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

In support of her claim, Ms. Isakson states that she disagrees with the auditing cardiologist's determination. In response, the Trust asserts that claimant did not rebut Dr. Oliner's findings that the freeze frames on which Dr. Brann relied did not reflect mitral regurgitation in real time and that the jet observed included non-regurgitant, low velocity signal. The Trust also contends that a low Nyquist setting and excessive color grain likely contributed to Dr. Brann's inaccurate evaluation of claimant's level of mitral regurgitation.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Abramson observed:

> I reviewed the transthoracic echocardiogram dated 7/26/02 from Echo Express, Inc. The left ventricle is markedly dilated with severely decreased systolic function; ejection fraction is in the range of 30-35%. The machine settings inappropriately maximize the mitral regurgitation jet. Also, the Nyquist limit is set at 51 cm/sec, which will increase the appearance of the mitral regurgitation more than a Nyquist limit set at 60 to 70 cm/sec. In addition, the color gain settings are set too high, which will increase the appearance of the mitral regurgitation. Despite this, by visual estimate, there appears to be mild mitral regurgitation. The technologist performed six measurements of the mitral regurgitant jet and two measurements of the left atrial area. The first three measured RJA of 3.6 cm^2, 3.9 cm^2, and 4.6 cm^2 include appropriate high velocity, regurgitant flow. The last three measurements were over traced and include low velocity, non-regurgitant flow.

> There was a left atrial area measurement of 25.1 cm^2, which was appropriately traced. The other left atrial measurement was not obtained at end-systole, thus the measurement was incorrect. Using these three RJA and the one LAA, I calculated RJA/LAA ratios of 14%, 16%, and 18%. All of these ratios are less than 20%, which is consistent with mild mitral regurgitation. I received the study as a continuous movie on a CD so I was unable to perform my own measurements.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. We disagree with claimant that the Green Form and the echocardiogram report submitted in connection with her claim provide a reasonable medical basis for Dr. Brann's representation of moderate mitral regurgitation. We are required to apply the standards delineated in the Settlement Agreement and Audit Rules. The context of those two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends. For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount

of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Oliner reviewed claimant's echocardiogram and determined that "[t]he RJA's are freeze frames that do not represent the mild [mitral regurgitation] seen in real time." He also observed that "[m]ost of the RJA's include substantial non-[mitral regurgitant] low velocity signal" and that the "[c]olor gain is excessive and Nyquist is borderline low." In addition, Dr. Abramson determined that three of the RJAs on the tape "were over traced and include low velocity, non-regurgitant flow." Dr. Abramson also determined that one of the LAA measurements on the echocardiogram tape "was not obtained at end-systole, thus the measurement was incorrect." Finally, she determined that the "machine settings inappropriately maximize the mitral regurgitation jet," i.e., the Nyquist was too low and the color gain settings were too high. Neither claimant nor Dr. Brann adequately disputed these findings.[10] Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation of moderate mitral regurgitation. To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement.

---

10. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Isakson's claim for Matrix Benefits and the derivative claims submitted by her children.